IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Examiner:
K.T. Venkateswara Rao	Bruce Edward Snow
Serial No.: 10/668,077	Art Unit: 3738
Filed: September 22, 2003	Confirmation No.: 1259

Title: Drug-Eluting Stent And Methods of Making Same

Mail Stop **Amendment**
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

AMENDMENT

Sir:

In response to the Office action dated May 21, 2007, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 7 of this paper.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (currently amended) A sleeve loaded with at least one therapeutic drug for the eventual release thereof at a treatment site within a body lumen, comprising:

a prefabricated patterned tubular sleeve portion having independent drug-loaded elements, the patterned tubular sleeve portion being releasably attached to an outer surface of a stent structure in an unexpanded condition, the stent structure having a longitudinal axis and a transverse cross-section defining a circumference, at least a portion of the patterned tubular sleeve portion being decoupled from the outer surface of the stent structure when the stent structure is in an expanded condition so that the independent drug-loaded elements are held against the body lumen by at least a portion of the patterned tubular sleeve portion, wherein the independent drug-loaded elements are positioned longitudinally across the outer surface of the stent structure and spaced apart from each other over the circumference ~~sleeve is not stretched when the stent structure expands from the unexpanded condition to the expanded condition~~.

2. (original) The sleeve of claim 1, wherein the patterned tubular sleeve portion is fabricated from a polymeric material.

3. (withdrawn) The sleeve of claim 1, wherein the patterned tubular sleeve portion is fabricated from a metallic material.

4. (original) The sleeve of claim 1, wherein the patterned tubular sleeve portion includes a plurality of depots.

5. (withdrawn) The sleeve of claim 3, wherein the patterned tubular sleeve portion includes a plurality of longitudinal channels.

6. (currently amended) ~~The sleeve of claim 1,~~ A sleeve loaded with at least one therapeutic drug for the eventual release thereof at a treatment site within a body lumen, comprising:

a prefabricated patterned tubular sleeve portion having independent drug-loaded elements, the patterned tubular sleeve portion being releasably attached to an outer surface of a stent structure in an unexpanded condition, at least a portion of the patterned tubular sleeve portion being decoupled from the outer surface of the stent structure when the stent structure is in an expanded condition so that the independent drug-loaded elements are held against the body lumen by at least a portion of the patterned tubular sleeve portion, wherein the sleeve is not stretched when the stent structure expands from the unexpanded condition to the expanded condition, and

wherein the patterned tubular sleeve portion is configured as a wave pattern.

7. (withdrawn) The sleeve of claim 1, wherein the patterned tubular sleeve portion is configured as a braided mesh pattern.

8. (withdrawn) The sleeve of claim 1, wherein the patterned tubular sleeve portion is configured as a longitudinal slot pattern.

9. (currently amended) The sleeve of claim 1, wherein upon expansion of the stent structure, the

patterned tubular sleeve portion completely releases from the outer surface of the stent structure.

10. (currently amended) The sleeve of claim 1, wherein upon expansion of the stent structure, the

patterned tubular sleeve portion has an opening in the range from about 0.1 mm^2 to about 4.0 mm^2 in area.

11. (currently amended) The sleeve of claim 1, wherein upon expansion of the stent structure, the patterned tubular sleeve portion has an opening in the range from about 0.3 mm to about 2.0 mm in length.

12. (original) The sleeve of claim 1, wherein the patterned tubular sleeve portion includes a pattern of struts interconnected to form the sleeve for contacting at least a portion of the walls of the body lumen.

13. (original) The sleeve of claim 12, wherein the struts have a radial thickness in the range form about 10 nanometers to about 10 micrometers.

14. (original) The sleeve of claim 12, wherein the struts have a width in the range from about 100 nanometers to about 100 micrometers.

15. (original) The sleeve of claim 1, wherein the patterned tubular sleeve portion has an elastic modulus in the range from about 0.05 megapascals to about 30.00 megapascals.

16. (original) The sleeve of claim 1, wherein the patterned tubular sleeve portion has a drug loading capacity in the range from about 0.1 micrograms to about 100 milligrams of therapeutic drug or agent.

17-18. (cancelled)

19. (withdrawn) An assembly for delivering a therapeutic drug within a body lumen, comprising:

a stent having an outer surface and being in an unexpanded condition mounted on a stent delivery catheter;

a prefabricated cover having a therapeutic drug selectively loaded into at least a portion of the cover;

the cover being releasably attached to the stent outer surface after the stent is mounted on the catheter assembly so that the drug is decoupled from the unexpanded stent; and

at least a portion of the cover detaching from the stent outer surface when the stent is expanded so that the drug loaded portion of the cover is pressed against the body lumen allowing the therapeutic drug to release into the body lumen.

20. (withdrawn) A filament cover loaded with at least one therapeutic drug for the eventual release thereof at a treatment site within a body lumen, comprising:

a plurality of individual filament strands arranged longitudinally around an outer surface of a stent structure in a spaced apart orientation, the plurality of individual filament strands each loaded with at least one therapeutic drug for the release thereof at the treatment site;

wherein the plurality of individual filament strands are held against the body lumen while the stent structure is in an expanded condition.

21. (withdrawn) The filament cover of claim 20, wherein the plurality of individual filament strands are attached to at least a portion of the outer surface of the stent structure.

22. (withdrawn) The filament cover of claim 20, wherein the plurality of individual filament strands include depots.

23. (withdrawn) The filament cover of claim 20, wherein the plurality of individual filament strands include longitudinal channels.

24. (withdrawn) The filament cover of claim 20, wherein the plurality of individual filament strands include undulations.

25. (withdrawn) A method for delivering a therapeutic drug within a body lumen, comprising:

providing a stent having an outer surface;

mounting the stent on a stent delivery catheter while in an unexpanded condition;

providing a prefabricated cover having a therapeutic drug selectively loaded into at least a portion of the cover;

releasably attaching the cover to the stent outer surface after the stent is mounted on the catheter assembly so that the drug is decoupled from the unexpanded stent;

detaching at least a portion of the cover from the stent outer surface when the stent is expanded so that the drug loaded portion of the cover is pressed against the body lumen; and

releasing the therapeutic drug into the body lumen.

26. (previously presented) The sleeve of claim 1, wherein each of the independent drug-loaded elements is releasably adhered to the outer surface of the stent structure in the unexpanded condition.

27. (new) The sleeve of claim 1, wherein the patterned tubular sleeve portion is configured as a wave pattern.

28. (new) The sleeve of claim 1, wherein the independent drug-loaded elements extend in a circumferential direction about the circumference of the stent structure and extend in a longitudinal direction to a greater extent than in the circumferential direction.

29. (new) The sleeve of claim 1, wherein after the stent structure expands from the unexpanded condition to the expanded condition, the independent drug-loaded elements are separated by gaps extending in a circumferential direction about the circumference of the stent structure and extending in a longitudinal direction to a greater extent than in the circumferential direction.

30. (new) The sleeve of claim 1, wherein the independent drug-loaded elements are not connected to each other after the stent structure expands from the unexpanded condition to the expanded condition.

31. (new) The sleeve of claim 1, wherein the stent structure includes a plurality of radially expandable cylindrical rings and each of the independent drug-loaded elements are positioned longitudinally across the plurality of cylindrical rings.

32. (new) The sleeve of claim 31, wherein at least one of the plurality of radially expandable cylindrical rings supports each of the independent drug-loaded elements.

REMARKS/ARGUMENT

Description of Amendments

Claims 1-16 and 19-32 are pending after entry of this Amendment. Claims 1, 6, and 9-11 are currently amended, and claims 27-32 are new. No new matter is introduced. The subject matter of amended claim 1 and new claims 28-32 is supported by the specification as originally-filed (see, for example, FIGS. 6A and 7B and paragraphs 72 and 73). Amended claim 6 is based on previously presented claims 1 and 6. New claim 27 is based on previously presented claim 6.

Reconsideration of the application and removal of the rejections are respectfully requested in view of the forgoing claim amendment and the remarks presented below.

Rejections under 35 U.S.C. §112

Claims 1, 2, 4, 6, 9-18, 26 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claims 17 and 18 were previously cancelled, so the rejection of those claims is moot.

The Examiner stated that the "claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." The Examiner then quoted the following portion of claim 1 (as previously presented):

> patterned tubular sleeve being releasably attached to an outer surface of the stent structure in an unexpanded condition, at least a portion of the patterned tubular sleeve portion being decoupled from the outer surface of the stent when the stent is in an expanded condition.

As best understood, the Examiner appears to contend that the above-quoted portion of claim 1 was not properly described in the application as filed. Applicant respectfully disagrees with any such contention. The above-quoted portion of claim 1 appears in the original version of claim 1 as filed. Paragraph 65 of the application as originally filed provides that "the polymeric sleeve decouples from the outer surface of the stent" and "the polymeric sleeve may be attached at selected locations or completely detached... The sleeve may be attached to the stent using conventional metal-polymer or polymer-polymer adhesion techniques known in the art." Paragraph 86 of the application as originally filed provides that "at least a portion of the cover is detached from the stent outer surface when the stent is expanded..." Accordingly, Applicant respectfully submits that the subject matter of claim 1 and its dependant claims are described in the application as filed in compliance with 35 U.S.C. §112, first paragraph.

Allowable Subject Matter

The Examiner stated that dependant claim 6 "is not rejected in view of art."

Applicant has rewritten claim 6 in independent form, including all limitations of previously presented claim 1. Accordingly, Applicant respectfully submits that claim 6 is patentably allowable over the cited references.

Rejections under 35 U.S.C. §102

I.

Claims 1, 2, 4, 9-18, 26 were rejected under 35 U.S.C. 102(e) as being anticipated by US 2003/0153901 ("Herweck").

Claims 17 and 18 were previously cancelled, so the rejection of those claims is moot.

Herweck fails to teach the limitation of claim 1 of "a prefabricated patterned tubular sleeve portion having independent drug-loaded elements, the patterned tubular sleeve portion being releasably attached to an outer surface of a stent structure in an unexpanded condition…"

The Office Action states: "1 (previously presented) A sleeve loaded 12…" As best understood, the Examiner appears to contend that the drug delivery panel 12 shown in FIGS. 1-15 of Herweck corresponds to "patterned tubular sleeve portion" of claim 1. However, Herweck does not disclose that the drug delivery panel 12 is tubular. Therefore, **the "patterned tubular sleeve portion" of claim 1 is patentably distinct from the drug delivery panel 12 of Herweck FIGS. 1-15**.

The Office Action also states: "a prefabricated patterned tubular sleeve portion having independent drug-loaded elements 12, 12a, etc…" As best understood, the Examiner also appears to contend that the drug delivery panel 12, 12a shown in FIGS. 1-15 of Herweck corresponds to the "independent-drug loaded elements" of claim 1. Herweck still fails to teach the "patterned tubular sleeve portion being releasably attached to an outer surface of a stent structure" of claim 1. Even if the Examiner contends that the "patterned tubular sleeve portion" is met by the radially expandable structure 10 (FIG. 1) or the vascular graft (FIG. 8) of Herwick, Herweck does not teach that the structure 10 or vascular graft is "releasably attached" to an outer surface of a stent structure. Therefore, **the "patterned tubular sleeve portion" of claim 1 is patentably distinct from the structure 10 and vascular graft of Herweck FIGS 1 and 8**.

For the reasons set forth above, Applicant respectfully submits that claim 1 is patentably allowable over Herweck. Claims 2, 4, 9-16, which depend from claim 1, are patentably allowably over Herweck for at least the same reason as claim 1.

If the rejections over Herweck are maintained, Applicant respectfully requests the Office to identify the "patterned tubular sleeve," the "independent drug loaded elements," and the "stent structure" of claim 1 in accordance with 37 CFR 1.104(c)(2), which provides that "[w]hen a reference is complex …, the particular part relied on must be designated as nearly as practicable."

II.

Claims 1, 2, 4, 9-18, 26 were rejected under 35 U.S.C. 102(b) as being anticipated by US 5,700,286 ("Tartaglia").

Claims 17 and 18 were previously cancelled, so the rejection of those claims is moot.

Claim 1 has been amended to recite:

> the stent structure having a longitudinal axis and **a transverse cross-section defining a circumference** …
>
> wherein independent drug-loaded elements are positioned longitudinally across the outer surface of the stent structure and **spaced apart from each other over the circumference**.

(emphasis added). Tartaglia fails to teach these limitations of claim 1. Tartaglia FIG. 3 shows a planar sheet or film 24 that can have slits 30. The Examiner has asserted that in Tartaglia, "the slits 30 produce independent elements." However, Tartaglia does not teach that the slits 30 result in a space between the Examiner's alleged independent elements. Therefore, **Tartaglia fails to teach that the alleged independent elements are "spaced apart from each other".** Even if the Examiner were to assert that the slits result in a space,

the alleged independent elements of Tartaglia are not "spaced apart from each other over the circumference" and, therefore, fail to meet the limitations of claim 1. Applicant draws the Examiner's attention to Tartaglia FIG. 2, which shows a transverse cross-sectional view of the film 24 when the stent 22 is in an expanded state. Tartaglia FIG. 2 shows no spacing between alleged independent elements. Accordingly, Applicant respectfully submits that claim 1 and claims depending therefrom are patentably allowable over Tartaglia.

Rejection under 35 U.S.C. §103(a)

Claims 1, 2, 4, 9-18, 26 were rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,707,385 ("Williams") in view of Tartaglia.

Claims 17 and 18 were previously cancelled, so the rejection of those claims is moot.

The Examiner stated that "Williams is silent regarding the sleeve having independent drug-loaded elements." Applicant respectfully submits that Williams is also silent regarding the limitation of claim 1 of independent drug-loaded elements "spaced apart from each other in a transverse cross-section of the patterned tubular sleeve, the transverse cross-section viewed after the stent structure expands from the unexpanded condition to the expanded condition." As previously discussed above, Tartaglia fails to teach this limitation of claim 1. Accordingly, Applicant respectfully submits that claim 1 and the claims depending therefrom are patentably allowable over Williams in view of Tartaglia.

Information Disclosure Statement filed September 1, 2004

Applicant thanks the Examiner for providing a copy of the subject IDS filed September 1, 2004 (dated January 15, 2004). The Examiner has stated that the subject IDS "contains cover pages but no 1449" (Office Action of May 24, 2006, page 2).

It is believed that the references referred to in the subject IDS are duplicative of the references cited in the first IDS filed in the present application, namely the IDS dated March 21, 2003. Since the IDS dated March 21, 2003 included form PTO/SB/08A, no 1449 or PTO/SB/08A form needs to be submitted for the subject IDS.

The references referred to in the subject IDS are believed to be duplicative of the references cited in the first IDS for the following reasons. First, the subject IDS states that "The references listed were previously submitted in parent application Serial No. 10/293,108." In the parent application, only one IDS was submitted prior to 2006, namely the IDS filed September 1, 2004 (dated March 21, 2003). Second, the same references are cited in both the parent IDS filed September 1, 2004 (dated March 21, 2003) and the present application's first IDS dated March 21, 2003.

Applicants have not received an indication that the Office has considered the references cited by Applicant in Form PTO/SB/08A that accompanied the present application's first IDS dated March 21, 2003. Accordingly, Applicants respectfully requests return of the Form PTO/SB/08A indicating consideration of the cited references.

Conclusion

In light of the foregoing remarks, this application is considered to be in condition for allowance, and early passage of this case to issue is respectfully requested. If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit

any overpayments to Deposit Account No. 05-0150.

Respectfully submitted,

Date: November 14, 2007

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